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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,113	03/10/2004	Myron Spector	1194-176	2494
6449 7590 04/20/2007 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			EXAMINER GUCKER, STEPHEN	
			ART UNIT 1649	PAPER NUMBER

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/20/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/20/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/796,113	<b>Applicant(s)</b> SPECTOR ET AL.	
	<b>Examiner</b> Stephen Gucker	<b>Art Unit</b> 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 February 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Response to Amendment***

1. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-7, 9-15, 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (US 5,837,278; "278") in view of Shimizu (US 6,090,117) and further in view of the abstracts of Hentz et al. and Rosen et al. for reasons of record and the following. The '278 patent discloses a single sheet of a resorbable sidewall material consisting essentially of a single layer collagen sheet material having a compact, smooth outer barrier surface so as to inhibit cell adhesion

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thereon and act as a barrier to prevent passage of cells there through, this sheet material further having a fibrous inner surface opposite the smooth barrier surface (column 1, line 51 to column 2, line 6) derived from collagen membrane peritoneal tissue (column 2, lines 52-60). This single layer collagen sheet material is identified as Bio-Gide ® by the instant specification (page 3, paragraphs 0017 and 0018), thereby meeting the limitations of the instant claims. The '278 patent does not disclose a nerve regeneration tube for connecting nerve ends having an inner diameter of about 0.5-5mm and a length of about 10-100mm formed from the single collagen sheet of the '278 patent, or a filling material comprised of a mixture of Type I and Type IV collagen, or collagen fibers having a substantially longitudinal orientation with respect to said tube, or a filling material including laminin as a nerve growth stimulant. Shimizu discloses a nerve regeneration tube comprising of at least three sheets of collagen (column 6, line 48 to column 7, line 50) but which is also about 1-8mm in inner diameter with a length about 28-35mm, but can differ according to the length of the severed portion of the nerve and the thickness of the nerve (column 7, lines 19-31; see also a 10mm long tube in Comparative Example 4), thereby meeting the limitations of the instant claims. Shimizu also teaches filling materials for a nerve regeneration tube comprising laminin and Type IV collagen (column 8, lines 40-55) and collagen Type I solution or fibers having a substantially longitudinal orientation with respect to said tube (column 7, line 55 to column 8, line 13; column 8, line 65 to column 9, line 48). Shimizu does not explicitly disclose a reasonable expectation of success of making a collagen nerve regeneration tube out of a collagen sheet of membrane. Both Hentz et al. and Rosen et

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al. teach in their abstracts the feasibility and likelihood of success of making collagen tubes out of collagen sheets or membranes. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the single sheet collagen material of the '278 patent to make a nerve regeneration tube out of collagen as taught by Shimizu because Shimizu employs at least three sheets of collagen to produce his nerve regeneration tube and by using a single sheet of collagen with the attractive features (one side smooth and inhibits cell permeation, the other side fibrous to promote biological regrowth) taught by the '278 patent, a simpler nerve regeneration tube can be produced that uses less material (single sheet as opposed to at least three sheets of collagen), is quicker and easier to produce, and would have the further advantage of economic savings due to lowered costs of production by reducing the need for at least three sheets of collagen to a single sheet of collagen. The combined references also establish a *prima facie* case of obviousness because the collagen material of the '278 patent has desirable features such as a smooth surface to inhibit cell adhesion on the outside with a fibrous surface to support cells on the inside and simply forming a tube out of this two-sided collagen material is *prima facie* obvious given that collagen nerve regeneration tubes were in use at least as way back as the 1980s, and the '278 patent collagen material is used as a single sheet to make a collagen nerve regeneration tube as opposed to at least three sheets of collagen which are used in the prior art of record. Finally, the advantageous characteristics of the two-sided collagen material of the '278 patent would suggest to and motivate the ordinary artisan to fashion the collagen material into a tube with a smooth outside and fibrous inside in order to promote axonal

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regeneration in the interior of the tube as indicated by Shimizu (column 7, line 55 to column 8, line 13; column 8, line 40 to column 9, line 63).

*Applicant's arguments filed 2/5/07 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The '278 patent discloses a single sheet of a resorbable sidewall material, and the previous Office Action repeated above explains the motivation of why one of ordinary skill in the art would find a single sheet advantageous (underlining for emphasis). Additionally, Applicant argues against the enablement of the instant invention by stating that Shimizu criticizes the use of collagen tubes for nerve regeneration! Instead of finding the instant invention or the '278 patent as being non-enabled, the Examiner's position is that the '278 patent is considered valid and enabled as a matter of law, and that a finding of obviousness does not equate with absolute certainty of the perfect functionality of the obvious invention, but that it is more likely than not that the combination of the references provides an operative embodiment with a reasonable, not absolute, expectation of success. The Examiner also notes that the reference does not state that collagen tubes are not enabled, but that satisfactory results have not been obtained, which merely indicates that collagen tubes work, but there is room for improvement for an undisclosed reason, which could be as simple as not working 100% of the time.*



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5. Claims 1-7 and 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (US 5,837,278; "278") in view of Shimizu (US 6,090,117) and further in view of the abstracts of Hentz et al. and Rosen et al. as applied above and further in view of Stensaas et al. (US 4,778,467, "Stensaas") for reasons of record and the following. None of Geistlich or Shimizu or Hentz et al. or Rosen et al. explicitly teach methods of forming tubes from collagen sheets, although Shimizu does teach a collagen nerve regeneration tube and Hentz et al. and Rosen et al. do describe making tubes from collagen sheets. Stensaas teaches methods of forming tubes for nerve regeneration (Figures 1 and 3A-3B, column 10, line 3 to column 11, line 5) with or without silicone rubber adhesive that meet the limitations of the instant claims (also see column 9, lines 1-16 and column 16, lines 54-66 (Figures 7A-7B) for overlapping edges). It would have been obvious to one of ordinary skill in the art at the time of the invention to employ the teachings of Stensaas to make various kinds of tubing (opposed edges, overlapping edges, etc.) out of a collagen sheet material because the other references, while teaching the desirability of doing so, lack explicit descriptions and drawings as to how to accomplish the actual construction of various types of tubes for nerve regeneration, which Stensaas does teach. The ordinary artisan, searching for information to fabricate nerve regeneration tubes, would find the teachings of Stensaas and find it *prima facie* obvious to use his disclosure in combination with the other references because Stensaas supplies the explicit teachings that the other references lack concerning nerve regeneration tube construction.

*Applicant's arguments filed 2/5/07 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The '278 patent discloses a single sheet of a resorbable sidewall material, and the previous Office Action repeated above explains the motivation of why one of ordinary skill in the art would find a single sheet advantageous (underlining for emphasis). Additionally, Applicant argues against the enablement of the instant invention by stating that Shimizu criticizes the use of collagen tubes for nerve regeneration! Instead of finding the instant invention or the '278 patent as being non-enabled, the Examiner's position is that the '278 patent is considered valid and enabled as a matter of law, and that a finding of obviousness does not equate with absolute certainty of the perfect functionality of the obvious invention, but that it is more likely than not that the combination of the references provides an operative embodiment with a reasonable, not absolute, expectation of success. The Examiner also notes that the reference does not state that collagen tubes are not enabled, but that satisfactory results have not been obtained, which merely indicates that collagen tubes work, but there is room for improvement for an undisclosed reason, which could be as simple as not working 100% of the time.*

6. Claims 1-15, 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (US 5,837,278; "'278") in view of Shimizu (US



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6,090,117) and further in view of the abstracts of Hentz et al. and Rosen et al. as applied above and further in view of Humes (US 5,429,938) for reasons of record and the following. None of Geistlich or Shimizu or Hentz et al. or Rosen et al. teach a mixture of Type I and Type IV collagen in a ratio of about 1:1 for supporting biological activity. Humes does teach the use of Type I and Type IV collagen in about 1:1 ratios to support biological activity (column 3, lines 65-66). It would have been obvious to one of ordinary skill in the art at the time of the invention to employ Humes' ratio of about 1:1 of Type I and Type IV collagen because the other references do not qualitatively teach specific amounts between Type I and Type IV collagen and the artisan would be motivated to look to the Humes reference to supply this missing information if said artisan was actually going to reduce to practice a combination of Type I and Type IV collagen because such information would be required during fabrication.

*Applicant's arguments filed 2/5/07 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The '278 patent discloses a single sheet of a resorbable sidewall material, and the previous Office Action repeated above explains the motivation of why one of ordinary skill in the art would find a single sheet advantageous (underlining for emphasis). Additionally, Applicant argues against the enablement of the instant invention by stating that Shimizu criticizes the use of collagen tubes for nerve*

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*regeneration! Instead of finding the instant invention or the '278 patent as being non-enabled, the Examiner's position is that the '278 patent is considered valid and enabled as a matter of law, and that a finding of obviousness does not equate with absolute certainty of the perfect functionality of the obvious invention, but that it is more likely than not that the combination of the references provides an operative embodiment with a reasonable, not absolute, expectation of success. The Examiner also notes that the reference does not state that collagen tubes are not enabled, but that satisfactory results have not been obtained, which merely indicates that collagen tubes work, but there is room for improvement for an undisclosed reason, which could be as simple as not working 100% of the time.*

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached at (571) 272-0867. The fax phone number for this Group is currently (571)-273-8300.

*SG*

Stephen Gucker

April 16, 2007

*[Signature]*  
JANET L. ANDRES  
SUPERVISORY PATENT EXAMINER